

**Remarks**

Claims 1(d) and 82(d) have been amended to recite "a preservative consisting of a mixture of methyl paraben and propyl paraben, wherein said methyl paraben is at a concentration of 0.1% to 0.2% and said propyl paraben is at a concentration of 0.01% to 0.05%," and to recite "wherein said polypeptide has KGF-2 activity." Claims 72 and 146 have been canceled without prejudice or disclaimer, claims 73 and 147 have been amended to depend from claims 1 and 82, respectively, and claims 54, 83, and 132 have been amended to correct minor spelling errors. Support for these amendments can be found throughout the specification as filed. Accordingly, no new matter has been introduced and entry of this amendment is respectfully solicited.

Claims 1-7, 9-33, 36-66, 71, 73-145, and 147-155 are pending.

Applicants thank the Examiner for initiating the telephone interview conducted on July 14, 2004, and indicating that the response submitted on February 23, 2004 overcame or obviated many of the outstanding objections and rejections. The Examiner stated during the interview that he still had concerns regarding the 35 U.S.C. § 103 rejection, and was considering making a new rejection of claims 1 and 82 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. Applicants address these issues below.

**I. Obviousness Rejection under 35 U.S.C. § 103**

The Examiner previously rejected claims 1-3, 5-17, 20-32, 36, 37, 71-73, 76, 80, 82-97, 100-115, 144-147 and 151-153 under 35 U.S.C. § 103 for allegedly being obvious over Human Genome Sciences (WO 96/25422; "HGS") in view of Chen et al., (Journal of Pharmaceutical Sciences, Vol. 85, No. 4, April 1996; "Chen") and Prestreleski et al. (U.S. Patent 5,580,856, "the '856 patent") for the reasons stated in Paper No. 21, page 11, paragraph 27.

In response, while Applicants respectfully disagree and maintain that the previously pending claims were not obvious, claims 1 and 82 have been amended to recite that the preservative "consists of a mixture of methyl paraben and propyl paraben, wherein said methyl paraben is at a concentration of 0.1% to 0.2% and said propyl paraben is at a concentration of 0.01% to 0.05%." As discussed in the response to the Patent Office mailed February 23, 2004, when the prior art discloses a large genus, there must be some motivation to seek out and acquire the claimed species from the vastly broad genus without

undue experimentation. *See In re Jones*, 958 F.2d 347, 351 21 U.S.P.Q.2d (BNA) 1941, 1943 (Fed. Cir. 1992). Without such motivation, a broad genus does not render claimed species obvious. *Id.* Moreover, even if references may be combined or modified, the resultant combination is not rendered obvious unless the prior art also teaches the desirability of the combination. Applicants maintain that the cited prior art provides no such motivation or desirability with respect to the claimed invention, especially with respect to the selection of the particular preservative mixture and concentrations recited in the claims.

Neither HGS, nor Chen, nor the '865 patent teach or suggest the use of the particular combination claimed in the instant invention. In particular, none of these references teach or suggest the use of a preservative that is a mixture of 0.1% to 0.2% methyl paraben and 0.01% to 0.05% propyl paraben. In addition, although the '865 patent includes KGF in a long list of proteins that can be used in the application in a wide range of concentrations and conditions and then further uses KGF in specific formulations, the '856 patent neither teaches nor suggests a means to select the particular combination of molecules at the particular ranges claimed in the instant application. Moreover, the '865 patent does not provide any motivation or expectation of success to select the particular combination of molecules at the particular ranges claimed in the instant application. Thus, to select the specific ranges of the specific combination claimed in the present invention would require more experimentation than just "mere optimization". Accordingly, these references do not render the instant invention obvious.

On the basis of the arguments set forth in the response submitted on February 23, 2004, and on the arguments set forth above, Applicant respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-3, 5-17, 20-32, 36, 37, 71-73, 76, 80, 82-97, 100-115, 144-147, and 151-153 under 35 U.S.C. § 103 for obviousness.

## **II. Enablement – 35 U.S.C. § 112, First Paragraph**

During the telephone interview, the Examiner indicated that a new rejection of claims 1 and 82 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement was being considered. The Examiner noted that this rejection would be obviated by the inclusion of the phrase "wherein said polypeptide has KGF-2 activity" in these claims.

In response, while Applicants maintain that the previously pending claims fully

complied with 35 U.S.C. § 112, first paragraph, Applicants have amended claims 1 and 82 to recite the language requested by the Examiner. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection under 35 U.S.C. § 112, first paragraph.

### *Conclusion*

Applicants respectfully request that the above-made remarks and amendments be entered and made of record in the file history of the instant application. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

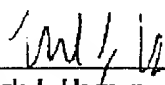
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As the instant supplemental amendment was expressly requested by the Examiner during the telephone interview of July 14, 2004, no reduction of patent term adjustment should be made pursuant to 37 C.F.R. § 1.704(c)(8).

Dated: July 16, 2004

Respectfully submitted,

By

  
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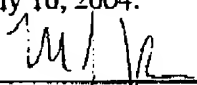
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I hereby certify that the above-listed correspondence is being facsimile transmitted to the United States Patent and Trademark Office on July 16, 2004.

  
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